Kentucky Department for Medicaid Services

Drug Review Options

The following chart lists the agenda items scheduled and the options submitted for review at the April 16, 2009, meeting of the Pharmacy and Therapeutics Advisory Committee

Item	Options for Consideration
New Drugs to Market: Kapidex™	Place this product non preferred with appropriate quantity limits in the PDL category titled Proton Pump Inhibitors.
New Drugs to Market: Sancuso®	Place this product non preferred with appropriate quantity limits in the PDL category titled Anti-Emetics: 5-HT3 Antagonists.
New Drugs to Market: Mozobil™	Since plerixafor will not be included on the KY PDL, allow this product to pay once the following criteria have been met: Plerixafor (Mozobil) will be approved if **both** of the following are true: 1. Diagnosis of autologous transplantation in patients with non-Hodgkin's lymphoma (NHL) **OR** multiple myeloma (MM); **AND** 2. Trail and failure of G-CSF mobilization monotherapy.
New Drugs to Market: Uloric®	Until this class can be reviewed for inclusion on the KY PDL, allow febuxostat to pay once the following criteria have been met: Febuxostat (Uloric) will be approved if **both** of the following are true: 1. Diagnosis of hyperuricemia associated with gout **AND** 2. Adequate trial (at least 3 months) of allopurinol without achievement of serum urate level below 6 mg/dL **OR** intolerance **or** contraindication to allopurinol.
New Drugs to Market: Toviaz™	Place this product non preferred with appropriate quantity limits in the PDL category titled Urinary Tract Antispasmodics.
New Drugs to Market: Rapaflo™	Place this product non preferred in the PDL category titled Alpha Blockers for BPH.
New Drugs to Market: Vectical™	Place this product non preferred in the PDL category titled Topical Agents for Psoriasis.
New Drugs to Market: Centany™	Place this product non preferred in the PDL category titled Dermatologics: Antibiotic Agents.
New Drugs to Market: Vimpat®	Based on the committee's previous recommendation for this class, place lacosamide preferred in the PDL category titled Anticonvulsants: Second Generation.
Immunosuppressants	1. DMS to select all unique chemical entities as preferred on the PDL. 2. Agents not selected as preferred will be considered non-preferred and will require Prior Authorization. 3. DMS to allow continuation of therapy if there is a paid claim in the past 90 days. 4. For any new chemical entity in the Immunosuppressant class, require a PA until reviewed by the PTAC.

Item	Options for Consideration
Sedative Hypnotics	1. DMS to select preferred agent(s) based on economic evaluation; however, at least one benzodiazepine with a quick onset, one with a long duration and one with an intermediate duration and chloral hydrate must be preferred. 2. Continue quantity limits (14 units for 14 days) on all sedative hypnotic agents with the exception of eszopiclone and zolpidem ER (30 units per 30 days). 3. For patients greater than 65 years old, eszopiclone, ramelteon, zaleplon, zolpidem, or zolpidem ER will automatically pay without PA 4. For patients less than 65 years old, any non preferred agent should pay after trial and failure of 2 preferred agents within the past 90 days. 5. If ramelteon is not selected as preferred, it will be approved for patients with history of drug/alcohol dependence. 6. Agents not selected as preferred will require PA. 7. For any new chemical entity in the sedative hypnotic class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.
Sedative Hypnotic Clinical Criteria	1. For patients greater than 65 years old, eszopiclone, ramelteon, zaleplon, zolpidem, or zolpidem ER will automatically pay without PA. 2. For patients less than 65 years old, any non preferred agent will automatically pay without PA after trial and failure of 2 preferred agents within the past 90 days. 3. For patients less than 65 years old and no claims history of sedative hypnotic use, non preferred products will be approved if: • There's a reason the patient cannot be changed to a medication within the same class not requiring prior approval (preferred medication). Acceptable reasons include: • Allergy to medications not requiring prior approval • Contraindication to or drug-to-drug interaction with medications not requiring prior approval • History of unacceptable/toxic side effects to medications not requiring prior approval • The requested non – preferred medication may be approved if both of the following are true: • If there has been a therapeutic failure on **two** preferred medication • The requested medication's corresponding generic (if covered by the state) has been attempted and failed or is contraindicated **SPECIAL CRITERIA FOR ROZEREM® (ramelteon)** Rozerem® will automatically be approved for patients with a history of drug/alcohol abuse.

Item	Options for Consideration
Topical Antifungals	1. DMS to select preferred agent(s) based on economic evaluation; however, at least agents representing multiple mechanisms of action as well as a combination product should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. Before utilization, the combination product miconazole/zinc oxide should be subject to trial and failure of conventional therapies for diaper dermatitis. 4. For any new chemical entity in the Topical Antifungal class, require a PA until reviewed by the P&T Advisory Committee.
Vusion® Clinical Criteria	Approval will be granted for individuals meeting all of the following criteria: • Recipient must have a diagnosis of diaper dermatitis; **AND** • Failed at least one conventional OTC or Rx therapy (zinc oxide, topical antifungal, hydrocortisone, A&D Ointment) for diaper dermatitis.
Growth Hormone	1. DMS to select preferred agents based upon economic evaluation; however, one preferred agent should be supplied in a pediatric convenient dosing form. 2. Continue to require clinical PA for all agents, preferred or non-preferred. 3. Allow continuation of therapy for agents selected as non-preferred for patients who have a history within the last 90 days. 4. For any new chemical entity in the Growth Hormone class, require a PA until reviewed by the P & T Advisory Committee.
Growth Hormone Clinical Criteria	Approvable diagnosis via ICD9 Override: 1. Growth Hormone Deficiency or Pituitary dwarfism 2. Pituitary disease from known causes such as pituitary tumor, pituitary surgical damage, hypothalamic disease, irradiation, or trauma such as Panhypopituitarism, Iatrogenic pituitary disorders, Other disorders of the pituitary and other syndromes of diencephalohypophyseal origin, Other disorders of the pituitary gland and craniopharyngeal duct 3. Turner's Syndrome 4. Chronic renal insufficiency & end-stage renal disease (pre transplant) 5. Prader-Willi Syndrome 6. Idiopathic Short Stature (meaning of unknown origin). Also called non-growth hormone deficient short stature 7. Small for gestational age 8. Short Stature Homeobox Gene 9. Noonan Syndrome 10. HIV wasting or cachexia 11. Short bowel syndrome **CRITERIA FOR APPROVAL OF A NON-PREFERRED GROWTH HORMONE:** Patient needs to: 1. Have ONE approvable diagnosis **AND** 2. Have a therapeutic failure to at least **TWO** preferred medications

Item	Options for Consideration
Penicillins	1. DMS to select preferred agent(s) based on economic evaluation; however, at least amoxicillin, ampicillin, dicloxacillin and penicillin V should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Penicillin class, require a PA until reviewed by the P&T Advisory Committee.
Penicillin/Beta-Lactamase Inhibitor Combinations	1. DMS to select preferred agent(s) based on economic evaluation; however, at least amoxicillin/clavulanate should be preferred on the PDL. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Penicillin/Beta-Lactamase Inhibitor Combination class, require a PA until reviewed by the P&T Advisory Committee.
First Generation Cephalosporins	1. DMS to select preferred agent(s) based on economic evaluation; however, at least cephalexin should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the First Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee.
Second Generation Cephalosporins	1. DMS to select preferred agent(s) based on economic evaluation; however, at least cefuroxime should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Second Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee.
Third Generation Cephalosporins	1. DMS to select preferred agent(s) based on economic evaluation; however, at least cefixime and cefpodoxime should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Third Generation Cephalosporin class, require a PA until reviewed by the P&T Advisory Committee.
Ketolides	1. DMS to select preferred agent(s) based on economic evaluation. 2. Maintain prior authorization criteria for telithromycin to ensure this product is being used for multi-drug resistant infections only. 3. Continue current quantity limit (10 days supply per month). 4. For any new chemical entity in the Ketolide class, require a PA until reviewed by the P&T Advisory Committee.

Item	Options for Consideration
Ketek® Clinical Criteria	1. Diagnosis of Community Acquired Pneumonia (CAP) OR Acute Exacerbation of Chronic Bronchitis AND 2. Must have previously used (within the past 28 days) ONE of the following: a. Penicillin (e.g., amoxicillin, amoxicillin-clavulanate, ampicillin-sulbactam, or piperacillin-tazobactam) b. 2nd or 3rd generation cephalosporins (e.g., cefuroxime, cefpodoxime, cefprozil, cefotaxime, ceftriaxone) c. Macrolide (e.g., azithromycin, clarithromycin, erythromycin) d. Fluroquinolone (e.g., levofloxacin, gatifloxacin, moxifloxacin) e. Tetracycline (e.g., doxycycline) f. Trimethoprim/sulfamethaxole (e.g., Bactrim) AND 3. Request is not for more than a 10 day supply. **Clinical Consideration** If Ketek® was initiated in the hospital; approve to complete the course of antibiotic therapy.
Tetracyclines	1. DMS to select preferred agent(s) based on economic evaluation; however, at least generic formulations of doxycycline, minocycline, and tetracycline should be preferred. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Tetracycline class, require a PA until reviewed by the P&T Advisory Committee.
Oxazolidinones	1. DMS to select preferred agent(s) based on economic evaluation; however, at least linezolid should be preferred. 2. Place PA criteria around linezolid to prevent overutilization and preserve it as a last line drug. 3. Continue appropriate quantity limits. 4. For any new chemical entity in the Oxazolidinones class, require a PA and quantity limit until reviewed by the P&T Advisory Committee.
Zyvox® Clinical Criteria	1. Diagnoses to approve: • Vancomycin-Resistant Gram Positive Infections (VRE) via current culture and sensitivity testing o Enterococcus faecium o Enterococcus faecalis • Methicillin-Resistant Staph Aureus Infections (MRSA) via current culture and sensitivity testing; **AND** 2. Request is **NOT** for more than a 14 day supply (Pass to RPh if days supply exceeds this) **Refer all other requests to a clinical pharmacist** **Clinical consideration:** If Zyvox was initiated in the hospital, approve to complete the course of antibiotic therapy. Number of days of hospital therapy is included in 14-day total therapy.

Item	Options for Consideration
Oral Antifungals	1. DMS to select preferred agent(s) based on economic evaluation; however, all currently available unique chemical entities should be preferred on the PDL. 2. Agents not selected as preferred will be considered non preferred and require PA. 3. For any new chemical entity in the Oral Antifungal class, require a PA until reviewed by the P&T Advisory Committee.
Terbenifine/Itraconazole Clinical Criteria	**Diagnoses to approve:** 1. Tinea corporis (body ringworm), Tinea cruris (jock itch), or Tinea pedis (athlete's foot): **a.** If the patient has **NOT** had a therapeutic failure on at least one topical antifungal medication, refer the request to a clinical pharmacist. **b.** If the patient has had a failure on at least one topical antifungal medication, approve: **i.** **terbinafine** tablets for once daily dosing for a 4-week continuous course of therapy **OR** **ii.** itraconazole capsules for once daily dosing for a 4-week continuous course of therapy. **c.** Patient can receive terbinafine or itraconazole automatically if diagnosis is **Tinea Capitis** for up to 4 weeks 2. Onychomycosis (fungal infection of the fingernails or toenails): a. Approval is based on initial vs. continuation or retreatment as follows: i. For the initial treatment of a fingernail or toenail infection (rather than continuation of therapy or retreatment) **AND ALSO** ii. For retreatment if there has been an interval of 3 months between the initial treatment of fingernail infection and a second treatment or an interval of 6 months between the initial treatment of toenail infection and a second treatment: 1. **Fingernail Infection**: Approve: a. terbinafine tablets for once daily dosing for a 6-week continuous course of therapy **OR** b. itraconazole capsules for **twice** daily dosing for an **6-week** course of therapy. 2. **Toenail Infection**: Approve: a. terbinafine tablets for once daily dosing for a 12-week continuous course of therapy **OR** b. itraconazole capsules for once daily dosing for a 12-week continuous course of therapy. 3. **For the treatment of a systemic or other serious fungal infection** (e.g., esophageal candidiasis, blastomycosis, aspergillosis, cutaneous sporotrichosis), approve the requested quantity for 6 months.